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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,706	01/23/2006	Shing Yue Chan	CU60405	7430

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1611	

NOTIFICATION DATE	DELIVERY MODE
08/25/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

US_cipkop@gsk.com

Office Action Summary	Application No.	Applicant(s)	
	10/565,706	CHAN ET AL.	
	Examiner	Art Unit	
	Isis A. Ghali	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-34* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-34 are pending.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-10, 23 and 24, drawn to orally dissolving film composition comprising enteric polymer, alkaline buffer and one active agent. Claims 23 and 24 drawn to method of using the film composition of claim 1.

Group II, claim(s) 11-17 and 22, drawn to multi-component orally dissolving film comprising (a) first component comprising alkaline buffering, and filler, and (b) second component comprising nicotine, enteric polymer and plasticizer. Claim 22 drawn to method of using the multi-component film composition of claim 11.

Group III, claim(s) 18-21, drawn to orally dissolving film comprising (a) first component comprising enteric polymer, alkaline buffering, and nicotine, and (b) second component comprising bioadhesive polymer. Claim 21 drawn to method of using the film composition of claim 18.

Group IV, claim(s) 25-30, drawn to oral dosage form comprising nicotine, bioadhesive material, and rapidly releasing sensory impact agent. Claims 29 and 30 drawn to method of using the composition of claim 25.

Group V, claim(s) 31-32, drawn to orally dissolving film comprising cosmetic active agent and polyvinyl alcohol-polyethylene glycol graft copolymer.

Group VI, claim(s) 33 and 34, drawn to method of making orally dissolving film.

2. The inventions listed as Groups I through VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Invention of Group I is distinct from invention of Group II as Group I does not require two different components as required by Groups II.

Invention of Group I is distinct from invention of Group III as Group I does not require bioadhesive polymer required by Group III.

Invention of Group I is distinct from invention of Group IV as Group I does not require bioadhesive polymer and rapidly releasing sensory impact agent required by Group IV. Further Group IV is not film as required by Group I.

Invention of Group I is distinct from invention of Group V as Group I does not require polyvinyl alcohol-polyethylene glycol graft copolymer required by Group V.

Invention of Group I is distinct from invention of Group VI as Group I does not require the process of making as required by Group VI, and the film composition of Group I can be made by simple mixing of all the components and film can be formed by extrusion or molding and not necessary by casting using two steps as required by invention VI.

Invention of Group II is distinct from invention of Group III as Group II does not require bioadhesive polymer required by Group III. Further the ingredients of each component of Group II is different from ingredients of each component of Group III.

Invention of Group II is distinct from invention of Group IV as Group II does not require bioadhesive polymer and rapidly releasing sensory impact agent required by Group IV. Further Group IV is not film as required by Group II.

Invention of Group II is distinct from invention of Group V as Group II does not require polyvinyl alcohol-polyethylene glycol graft copolymer required by Group V.

Invention of Group II is distinct from invention of Group VI as Group II requires plasticizer in the component comprising the active agent and enteric polymer and requires nicotine as active agent, while the method of Group VI does not require plasticizer or nicotine. Further the film of invention II can be made by extrusion or molding and not necessary by casting as required by invention VI.

Invention of Group III is distinct from invention of Group IV as Group III does not require the rapidly releasing sensory impact agent required by Group IV. Further the dosage form of invention IV does not require two components or film as required by invention III.

Invention of Group III is distinct from invention of Group V as Group III does not require polyvinyl alcohol-polyethylene glycol graft copolymer required by Group V.

Invention of Group III is distinct from invention of Group VI as Group III requires bioadhesive polymer and nicotine that not required by the method of invention VI. Further the film of invention III can be made by extrusion or molding and not necessary by casting as required by invention VI.

Invention of Group IV is distinct from invention of Group V as Group IV does not require polyvinyl alcohol-polyethylene glycol graft copolymer required by Group , and additionally, Group V does not require bioadhesive and the rapidly releasing sensory impact agent required by Group IV. Furthermore, invention IV is a dosage form and not film, while invention V is a film.

Invention of Group IV is distinct from invention of Group VI as the dosage form of Group IV requires rapidly releasing sensory impact agent and bioadhesive that not required by Group VI. The dosage form of Group IV can be made by simple mixing of all the components as Group IV does not require film that is formed by casting as required by invention VI.

Invention of Group V is distinct from invention of Group VI as Group VI does not require polyvinyl alcohol-polyethylene glycol graft copolymer required by Group V. The film composition of Group V can be made by simple mixing of all the components and film can be formed by extrusion or molding and not necessary by casting as required by invention VI.

To summarize: Group I does not require any of the specific technical features of Groups II through VI. Group II has specific technical feature of having two components and each component has specific ingredients not required by any other Group. Group III has the specific technical feature of having two components and one of them has bioadhesive. Group IV has the specific technical feature of having bioadhesive and rapidly releasing sensory agent and does not require film as required by all other groups. Group V has the specific technical feature of having polyvinyl alcohol-polyethylene glycol graft copolymer. Group VI has specific technical feature of not requiring any specific active agent and film formed by casting process.

3. Because the above restriction/election requirement is complex, a telephone call to the applicant's agent to request oral election was not made. See MPEP, Sec.812.01.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not

commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Correspondence

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Isis A Ghali/
Primary Examiner, Art Unit 1611

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